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9-28-93 DATE BY

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DOE ORDER # 5400

RF-46522 (Rev. 7/93)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION VIII
999 18th STREET - SUITE 500
DENVER, COLORADO 80202-2466

SEP 28 1 07 PM '93

SEP 21 1993

EG&G
ROCKY FLATS PLANT
CORRESPONDENCE CONTROL

Ref: 8HWM-FF

Mr. Richard Schassburger
U.S. Department of Energy
Rocky Flats Office
P.O. Box 928
Golden, CO 80402-0928

Re: Statistical Comparisons to Background at Rocky Flats

Dear Mr. Schassburger:

EPA reviewed the July 30, 1993, letter report prepared by Dr. Richard Gilbert which describes and illustrates a process for comparing environmental data to background data at the Rocky Flats Plant. We received the September 2, 1993 revised figure for Task 4 of the report. Our enclosed comments (Enclosure 1) are based on these two documents.

EPA accepts the recommendations of Dr. Gilbert and is ready to begin working with DOE, its contractors, and CDH to implement the recommendations immediately. Most of our comments concern the details of implementation. Achieving consensus on these details is the major task ahead. We urge DOE to begin and to carefully manage this process. As Dr. Gilbert suggests, statisticians should be full team members and participate in the discussions. We have enclosed a list of items we feel are the major topics on which to reach consensus (Enclosure 2). Our point of contact on this matter is Bonnie Lavelle, (303) 294-1067.

Sincerely,

Martin Hestmark

Martin Hestmark, Manager
Rocky Flats Project

Enclosures

cc: Gary Baughman, CDH
Joe Schieffelin, CDH
Bruce Thatcher, DOE
Dennis Smith, EG&G
Mike Gansecki, 8HWM-HW
Susan Griffin, 8HWM-SM

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GENERAL COMMENTS

Overall, the report is outstanding. It succinctly outlines a comprehensive paradigm for the background analysis of inorganic chemicals at RFP. It is obvious that the multitiered approach, incorporating specific data quality objectives, presentation and graphic analysis, and a series of six statistical tests has been well thought-out and all possible scenarios considered and problems anticipated. It directly addresses the predominant contentious and divisive issue, the proper application of the upper tolerance limit (UTL) approach that has been advanced by DOE.

On a purely technical level, the approach is well-balanced. However, the report appears to be overly concerned with possible Type I or false positive errors and not as concerned with Type II or false negative errors. From a risk assessment standpoint, a Type I error can be easily managed if it is unknowingly included in the risk assessment since the analysis can be revisited and professional judgment applied if the risk associated with the chemical in question proves unacceptable. In contrast, a Type II error cannot be so easily managed. If a Type II error is made, the chemical will be incorrectly eliminated early in the COC selection process and will not be further considered. Although it is desirable to minimize or eliminate both types of errors from the analysis, from a public health perspective it is preferable to make a Type I error. Chemicals included in the risk assessment from a Type I error will not automatically be remediated. EPA recommends that for risk assessment, sampling designs should specify the probability of a Type I error as 20% or less and the probability of a Type II error as 10% or less. This is an important item to reach consensus on between EPA, CDH, and DOE.

One additional problem that is not addressed in Dr. Gilbert's report, perhaps because it was outside the scope of work, involves data aggregation. This is a fundamental issue that has yet to receive the proper amount of focused attention. Without an established methodology for aggregating data within different environmental media, the time and effort expended in executing the sophisticated statistical approach presented in this report will be misspent. Although the report touches on some aspects of this broad problem, it does not directly discuss the issue. Therefore, EPA, CDH, and DOE need to address it.

If the agencies can agree that the above concerns will be addressed, the background analysis approach developed by Dr. Gilbert provides a well-balanced methodology that will, if implemented properly, lead to a robust background analysis. This objective, scientific approach will result in verifiable conclusions, expedite the review and comment period, and prevent an overreliance on professional judgment.

SPECIFIC COMMENTS

1. Page 2, Seventh Bullet. It is suggested that the same field sampling and laboratory procedures be used for both background and site data. The statement should be extended to include data aggregation. Past review of RFP data from operable units showed inconsistencies in the methodology used to aggregate data. Problems encountered at this phase will be magnified at later stages of the background analysis.

2. Page 4, Task 1, Observation 1, Third Bullet. This statement suggests that background analysis should be the initial step in selecting COCs. This is consistent with the COC selection methodology developed for Rocky Flats by DOE, EPA, and CDH. However, in order to manage DOE's effort in background comparisons, we point out that it is not necessary to carry all chemicals through an elaborate, time-consuming statistical analysis if they can be eliminated as essential nutrients or as infrequently detected chemicals. It may be more cost-effective and expeditious to simply eliminate chemicals on the basis of these two preliminary criteria than to conduct a background analysis only to eliminate them later based on the background analysis. We suggest that DOE consider this in the development of a plan to implement Dr. Gilbert's approach.

3. Page 5, Task 1, Observation 4, Second Bullet. This statement expressed concern about measurements that are less than the contract required detection limits (CRQL) but above instrument detection limits (IDL). According to Risk Assessment Guidance for Superfund, Human Health Evaluation Manual, Volume I, Part A , these measurements should be "J" coded and interpreted as estimated values. They should not be viewed as nondetected chemicals. If they are currently classified as nondetect chemicals in the RFP background geochemical report, the entire validation process currently in place should be reevaluated.

4. Page 9, Paragraphs 3 and 4. The essence of this discussion is that a hot measurement (HM) concentration should serve as a "safety net" that can prevent "hot spots" from passing unnoticed in a risk assessment. It should be noted that this need has been previously recognized and was addressed in the original flow chart devised during the summer 1992 meetings involving EPA, DOE, and CDH. At that time, it was agreed that a risk-based concentration (RBC) would effectively serve as the "hot measurement." Although a UTL has some utility in identifying hot spots, there is no need to conduct a lengthy analysis if the highest detected concentrations do not exceed a predetermined RBC and pose no unacceptable human health risks. Thus, it is possible to have measurements above the UTL but below an RBC in which case there would be little reason to consider the chemical further.

5. Page 10, Third and Fourth Bullet. This statement refers to lowering the potential for a Type I, false positive error by using a 99 percent UTL on the 99 percentile. However, this concern is not properly balanced against the potential for a Type II

error. A false negative could have profound consequences on the risk assessment and subsequent remedy selected for the site.

6. Page 11, Second Paragraph. This paragraph suggests that data quality objectives (DQOs) be established at the design stage of the studies. Although this is a relevant comment in the context of planning a background analysis, the background and most of the OU planning and sampling has already been completed. Thus, this comment is appropriate in theory but there is little chance for implementation. Revitalized effort should be directed to establishing DQOs where they were not previously established, and analyzing whether the sampling efforts completed to date have succeeded in meeting these DQOs. DOE, EPA, and CDH will need to look at options for correcting the situation if the DQOs have not been met.

7. Task 4, Flow Chart for Comparing OU Data to Background. With a minor exception, this flow chart adequately describes the framework for a background analysis. The exception is an inadequate description of appropriate conditions under which particular statistical tests should applied. Explicit guidelines for the application of specific statistical tests under well-defined conditions should be presented to circumvent future misunderstandings. It would be highly useful for EPA, DOE, and CDH to agree to a predetermined paradigm in which all possible circumstances and conditions have been anticipated and the appropriate statistical tests identified. Knowing in advance what particular test will be applied under what circumstances will prevent protracted discussions and possible disagreements.

IMPLEMENTATION ISSUES

1. EPA, DOE, and CDH must reach consensus on procedures for defining non-detects

2. EPA, DOE, and CDH must reach consensus on what hot measurement value should be used

3. EPA, DOE, and CDH must establish data quality objectives which address acceptable power and confidence levels, required detection limits, and anticipated data aggregation.

4. EPA, DOE, and CDH must revisit the assumptions which Dr. Gilbert lists on page 2 of his cover letter. Are these assumptions valid? What are the consequences if the assumptions are violated? Can this be handled in an uncertainty analysis?

5. EPA, DOE, and CDH must reach consensus on a paradigm for implementation. The issues to be resolved include:

    a. the appropriate background data sets by analyte, medium, and location

    b. how to deal with clearly non-random (e.g, spatial) patterns

    c. measurement errors and multiple non-detects

    d. structure for the formal statistical tests

    e. data aggregation for comparison in the statistical tests